The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on General Government

BILL:	SB 954
INTRODUCER:	Senator Passidomo
SUBJECT:	State Employees' Prescription Drug Program
DATE:	February 7, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.	McVaney/Davis	Betta	AGG	**Recommend: Favorable**
3.			AP	

I. Summary:

SB 954 directs the Department of Management Services to implement formulary management cost-saving measures in the State Employees' Prescription Drug Program. The cost-saving measures may exclude prescription drugs but may not restrict access to the most clinically appropriate, clinically effective, lowest net-cost prescription drugs. The measures must also permit a specified prescribing practitioner to indicate when an otherwise excluded drug is medically necessary and cannot be substituted.

The bill removes a provision authorized in ch. 99-255, L.O.F., which prohibits the implementation of a prior authorization program or a restricted formulary program on a non-HMO enrollee's access to certain prescription drugs.

Implementation of a closed formulary for the State Employees' Prescription Drug Program is expected to result in an indeterminate but significant increase in prescription drug rebates paid into the State Employees Health Insurance Trust Fund. The implementation is expected to decrease pharmaceutical claims paid from the State Employee Health Insurance Trust Fund by an indeterminate but significant amount.

The bills takes effect January 1, 2019.

II. Present Situation:

State Group Health Insurance Program Background

The State Group Health Insurance Program (state program) is created by s. 110.123, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services (DMS). The state program is an optional benefit for all state employees, including all state agencies, state universities, the court system, and the Legislature. The state

program includes health, life, dental, vision, disability, and other supplemental insurance benefits.

The state program typically makes program changes on a plan year basis, January 1 through December 31. Benefit changes are subject to approval of the Legislature. Typically, the Legislature includes direction to the DMS that the benefits provided in the current benefit documents continue during the next plan year. This statement is used by the Legislature to resolve issues at impasse between the State of Florida and its unionized employees.

Health Plan Options

The state program provides employees with two types of health plans: health maintenance organizations (HMOs) and preferred provider organizations (PPOs). The PPO is the statewide, self-insured health plan administered by Florida Blue, whose current contract is effective from the 2015 through 2018 plan years. The administrator is responsible for processing health claims, providing access to a Preferred Provider Care Network, managing customer service, utilization review, and case management functions.

The standard health maintenance organization (HMO) plan is an insurance arrangement in which the state has contracted with multiple statewide and regional HMOs.[1] Currently, there are four HMO vendors participating who were awarded contracts with initial terms of three years (January 1, 2018, through December 2020) with annual renewal options for up to three additional years. Only one HMO vendor is available in each county. Three of the HMOs vendors (Aetna, AvMed, and United Health Care) are under contract using a self-insured financial model and one HMO (Capital Health Plan) is under contract using a fully-insured model.

State Prescription Drug Plan

The state program also has a pharmacy benefit for members of the plan. The program covers all federal legend drugs (open formulary) for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis and multiple sclerosis. Specialty drugs often require special handling (e.g., refrigeration during shipping) and administration (such as injection or infusion).

The DMS has contracted with CVS Caremark as the pharmacy benefits manager (PBM) to administer the State Employees' Self-insured Prescription Drug Program pursuant to s. 110.12315, F.S. The table below shows the financial impact of the prescription drug program.

(in $ millions)	**2017-18**	**2018-19**	**2019-20**	**2020-21**	**2021-22**
PPO-PBM Rebates	$56.4	$58.1	$59.9	$61.8	$63.7
HMO-PBM Rebates	$50.1	$53.3	$56.8	$60.6	$64.6
Total Rebates	$106.5	$111.4	$116.7	$122.4	$128.3
PPO Pharmacy Claims	$364.6	$409.9	$470.8	$542.4	$624.9
HMO Pharmacy Claims	$295.4	$338.0	$401.9	$479.8	$572.4

[1] Department of Management Services, MyBenefits, *2018 Health Plan Options*, https://www.mybenefits.myflorida.com/health/2018_benefit_options/2018_health_plan_options (last visited Jan 22, 2018). The current contracted HMOs are Aetna, AvMed, Capital Health Plan, and United Healthcare.

Total Pharmacy Claims	$660.0	$747.9	$872.7	$1,022.2	$1,197.3

The cost to a member for a drug varies based on the health plan (standard plan or high deductible plan) in which a member is enrolled and on the type of drug (generic, a preferred brand-name, or a non-preferred brand-name).[2] The following chart depicts the member's cost.

Copayments or Coinsurance for State Employee Prescriptions and 90-Day Maintenance Medications[3]						
	Standard PPO[4] Standard HMO			**High Deductible HMO High Deductible PPO**		
	Retail (30 day)	***Mail Order (90 days)***	***Retail (90 days)***	***Retail 30 day***	***Mail Order 90 day***	***Retail 90 day***
Generic	$7	$14		30%		
Preferred Brand Name[5]	$30	$60		30%		
Non-Preferred Brand Name	$50	$100		30%		

The health plan currently covers all federal legend drugs[6] (open formulary) for covered medical conditions and provides very limited utilization review and clinical review for traditional or specialty prescription drugs.

The current health plan also covers compounded medications. Compounded medications combine, mix, or alter the ingredients of one or more drugs or products to create another drug or product. The plan only covers the federal legend drug ingredient of a compounded medication when all of the following criteria are met:

- The compounded medication is not used in place of a commercially available federal legend drug in the same strength and formulation, unless medically necessary;
- The compounded medication is specifically produced for use by a covered person to treat a covered condition; and

[2] Department of Management Services, *MyBenefits, Prescription Drug Plan*, https://www.mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last visited Jan. 18, 2018).

[3] Maintenance medications are considered those prescriptions commonly used to treat conditions that are considered chronic or long-term. These conditions require regular or on-going use of the drugs. Some examples include those medications that treat heart disease, diabetes, asthma, or heart disease.

[4] Members enrolled in a state employee PPO plan must fill their maintenance medications through the mail order pharmacy or a participating 90-day retail pharmacy after three fills at a 30-day retail pharmacy. *See* Department of Management Services, Prescription Drug Plan https://www.mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last visited Jan. 18, 2018).

[5] Members, who request a preferred brand-name drug when a generic is available, must pay the difference between the generic cost and the preferred name-brand cost, plus the appropriate copayment or coinsurance. If the prescribing physician writes on the prescription that the preferred brand is medically necessary or to "dispense as written" and the reason, the member pays only the appropriate brand copayment or coinsurance. *See* Department of Management Services, *Frequently Asked Questions*, https://www.mybenefits.myflorida.com/health/resources/faq_s/frequently_asked_questions_prescription_drug_plan (last visited Jan. 19, 2018).

[6] A legend drug is defined as any drug approved by the U.S. Food and Drug Administration and that are required by federal or state law to be dispensed to the public only on prescription of a licensed physician or other licensed provider.

- The compounded medication, including all sterile compounded products, is made in compliance with ch. 465, F.S., the Florida Pharmacy Act.[7]

Currently, the law prohibits the program from implementing a restricted formulary or prior authorization process on the non-HMO component of the State employees' Prescription Drug Program.[8]

National health spending on prescription drugs is projected to peak in 2018 at 7.6 percent, as fewer brand-name drugs are expected to lose patent protection and is expected to grow at an average of 6.3 percent a year in the private marketplace for 2016 through 2025.[9]

Formulary Development

Formularies are developed by a pharmacy and therapeutics (P&T) committee or an equivalent entity within health plans, PBMs, hospitals, government agencies, and Medicare and Medicaid programs. The P&T committee determines which medications and related products should be listed on the formulary. The P&T committee is composed of primary care and specialty care physicians, pharmacists and other professionals in the health care field and can include nurses, legal experts, and administrators.[10] In order to keep up to date on newly approved medications from the United States Food and Drug Administration the P&T committee should meet regularly to review newly released drugs and classes of drugs. As part of that review process, the P&T committee reviews some or all of the following:

- Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;
- FDA-approved prescribing information and related FDA information including safety data;
- Relevant information on use of medications by patients and experience with specific medications;
- Current therapeutic use and access guidelines and the need for revised or new guidelines;
- Economic data, such as total health care costs, including drug costs;
- Drug and other health care cost data (not all P&T committees review drug specific economic data); and
- Health care provider recommendations.[11]

Florida uses a P&T committee in its Medicaid program.[12] Membership on its committee includes physicians, pharmacists, and a consumer. The Medicaid preferred drug list is a listing of cost-effective, safe, and clinically efficient medications for each of the therapeutic classes on the list

[7] Department of Management Services, *My Benefits, Frequently Asked Questions – Prescription Drug Plan,* https://www.mybenefits.myflorida.com/health/resources/faq_s/frequently_asked_questions_prescription_drug_plan (last visited Jan. 19, 2018).
[8] Ch. 99-255, s. 8, Laws of Fla.
[9] Centers for Medicare and Medicaid Services, National Health Expenditure Projections 2016-2025, *Forecast Summary,* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf (last visited Jan. 19, 2018).
[10] Academy of Managed Care Pharmacy, *Formulary Management*, http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (last visited Jan. 19, 2018).
[11] *Id.*
[12] Section 409.91195, F.S.

and is posted on the Agency for Health Care Administration's website.[13] Medicaid recipients may appeal any drug formulary decisions using the Medicaid fair hearing process.[14]

III. Effect of Proposed Changes:

Section 1 directs the DMS to implement formulary management cost saving measures in the State Employees' Prescription Drug Program as established in s. 110.12315, F.S. The measures must require that the prescription drugs be subject to formulary inclusion or exclusion, but may not restrict access to the most clinically appropriate, clinically effective, and lowest net-cost prescription drugs.

The formulary program must allow an excluded drug to be included if a physician, an advanced registered nurse practitioner, or a physician assistant prescribing a pharmaceutical clearly states that the excluded drug is medically necessary and cannot be substituted.

According to the DMS, the CVS/Caremark formulary for 2018 covers the majority of generic drugs on the market as well as approximately 5,400 brand name drugs (preferred, non-preferred, and specialty). The 2019 formulary also excludes 159 drugs, test strips, insulin syringes, and pen needles that will require prior authorization or clinical review before those items will be covered.[15] By October of each year, CVS/Caremark announces the therapeutic classes and the specific drugs that will be affected by formulary changes.

Section 2 repeals s. 8 of ch. 99-255, L.O.F., which had prohibited the use of a prior authorization program or a restricted formulary for members in the PPO Plan.

Section 3 provides that the bill takes effect January 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[13] *See Florida Medicaid Preferred Drug List (PDL),* http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/fmpdl.shtml (last visited Jan. 19, 2018).
[14] Section 409.91195(11), F.S.
[15] Department of Management Services, *Senate Bill 954 Analysis* (November 27, 2017).

D. Other Constitutional Issues:

The separation-of-powers doctrine prevents the Legislature from delegating its constitutional duties. An invalid delegation of authority violates the principle of separation of powers mandated in the Florida Constitution. When delegating a regulatory responsibility, the Legislature must provide the agency with adequate standards and guidelines. The executive branch "must be limited and guided by an appropriately detailed legislative statement of the standards and policies to be followed."

In Askew v. Cross Key Waterways, the Florida Supreme Court acknowledged that "[w]here the Legislature makes the fundamental policy decision and delegates to some other body the task of implementing that policy under adequate safeguards, there is no violation of the [separation of powers] doctrine . . . ." If legislation lacks guidelines, and "neither the agency nor the courts can determine whether the agency is carrying out the intent of the Legislature in its conduct, then, in fact, the agency becomes the lawgiver rather than the administrator of the law."

The bill grants authority to the DMS or its PBM vendor to determine whether a prescription drug and supply will be available under the State Employee Prescription Drug Program. The bill does not specify any standards or policies to guide the DMS or the PBM in excluding or including the prescription drugs and supplies.

This may be more problematic in that health insurance coverage is typically a term and condition of employment and a mandatory subject of collective bargaining. Under Florida law, the Legislature is the final arbiter in the collective bargaining process. Under this bill, management (DMS) can decide unilaterally (without consultation or negotiation with the collective bargaining representatives) to exclude particular prescription drugs from the state program even though the Legislature has deemed those drugs included within the state program.

In order to ensure the formulary is implemented within constitutional parameters, the Legislature may consider establishing standards and guidelines for the DMS and the PBM in determining the exclusion or inclusion of prescribed drugs and supplies. In addition, to address the potential collective bargaining process issues, the Legislature may consider establishing a process that allows legislative oversight or approval prior to implementation of the closed formulary.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The impact to the private sector is twofold. First, implementation of a closed formulary will require the substitution of one drug or supply for another. This will affect the

members of the state plan. If CVS/Caremark's 2018 Standard Control Formulary[16] were implemented for the state program during the current plan year, up to 84,043 non-specialty prescriptions and 513 specialty prescriptions would be affected unless the prescriber indicates the drug is medically necessary or engages the prior authorization process. In terms of member impacts, 31,047 members of the state program would be affected.

The second impact will fall upon the pharmaceutical industry. Implementation of a closed formulary presumably gives the PBM a stronger bargaining position when negotiating rebates with the pharmaceutical industry. A pharmaceutical supplier may agree to pay higher rebates to ensure its drugs remain available within CVS/Caremark's formulary.

C. Government Sector Impact:

Implementation of a closed formulary in the State Employee Prescription Drug Program will result in indeterminate savings on pharmacy costs. The magnitude of the potential savings is unknown given the physician's ability to prescribe outside the formulary if the drug is medically necessary and cannot be substituted.

Implementation of a closed formulary may result in greater PBM rebates generated as revenues to the State Employee Health Insurance Trust Fund. The magnitude of the potential new rebates is unknown but expected to be significant.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 110.12315 of the Florida Statutes.

This bill repeals section 8 of chapter 99-255, Laws of Florida.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

[16] CVS/Caremark, *Prescribing Guide – Standard Control 2018* (January 2018) https://www.caremark.com/portal/asset/prescribing_guide.pdf (last visited Jan. 19, 2018).

B. Amendments:

None.